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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,417	07/03/2001	Michael R. Rosen	65219-A/JPW/PJP	3315

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	14

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,417	ROSEN ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-35* is/are pending in the application.

4a) Of the above claim(s) *4-8,10,12,17-31,33,35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9,11,15,16,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/7/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11,12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Final Rejection

Claims 1-12 and 15-35 are pending examination.

Applicant's traversal, the amendment to claims 1, 9, and 15, the cancellation of claims 13 and 14, the addition of claims 32-35 in paper no. 13 filed on 7/7/03 is acknowledged and considered.

The international search report has been considered.

Election/Restrictions

This application contains claims 4-8, 10, 12, 17-31, 33, and 35 drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

Applicant's arguments, see paper no. 7, filed 7/7/03, with respect to objection have been fully considered and are persuasive. The objection to the specification has been withdrawn because of the amendment to the abstract.

Claim Objections

Applicant's arguments, see paper no. 7, filed 7/7/03, with respect to objection have been fully considered and are persuasive. The objection to the claims 14 and 15 has been withdrawn because of the amendment to claim 15 and the cancellation of claim 14.

Claim Rejections - 35 USC § 112

Applicant's arguments, see paper no. 7, filed 7/7/03, with respect to 112 first paragraph rejection have been fully considered and are persuasive. The rejection to the Claims 1-3, 9-10, and 13-16 has been withdrawn because of the amendment to claims 1, 9, and 15 and the cancellation of claims 14 and 15. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claims 1 and 15.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 9, 11, 15, 16, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are directed to assaying whether an agent affects heart rate of a cardiac cell comprising a) contacting a cardiac cell *in vitro* with an agent to cause a sustainable heart rate and

b) measuring the heart rate after step a); c) contacting the cardiac cell with an agent to be assayed for its effect on the heart rate and d) measuring the heart rate after step c) and e) comparing the difference between step b) and step d).

The specification teaches measuring pacemaker current in isolated cardiac cells using transfection methods comprising contacting the isolated cardiac cells with a nucleic acid encoding HCN1, HCN2, or HCN4 or coexpressing HCN1 or HCN2 with MiRP1. However, the claims read on measuring the heart rate of a cardiac cell *in vitro* and the as-filed specification does not provide sufficient guidance or factual evidence for practicing the claimed methods. The specification does not provide a working example of the claimed method. The as-filed specification does not provide sufficient guidance and/or factual evidence to reasonably correlate using isolated cardiac cells and measuring pacemaker current to making and using an assay using a cardiac cell *in vitro* and measuring the heart rate. One skilled in the art would understand that for the claimed methods to be enabled for measuring the heart rate; a heart would have to be fully functional and the specification lacks guidance for what method steps and materials are required for one skilled in the art to use (or maintain) a heart to practice the claimed methods. The state of the art is absent for teaching how to measure heart rate in a cardiac cell *in vitro* as set forth in the claims. One skilled in the art understands that the heart rate is the amount of heartbeats over a certain time length (e.g., minute). In view of the art of record, an *in vitro* cardiac cell cannot produce a heartbeat. The specification does not provide sufficient guidance for reasonably correlating measuring pacemaker current to measuring heart rate of a cardiac cell *in vitro*. Thus, it would take one skilled in the art an undue amount of experimentation to

practice the claimed methods because the specification does not provide the method steps and materials required for measuring the heart rate of an isolated cardiac cell.

As a result, it is not apparent how one skilled in the art determines, without undue experimentation, which of the claimed methods are considered enabled, how is it apparent as to how one skilled in the art, without any undue experimentation, practices any method as contemplated by the claims, particularly given the unpredictability of making and using methods of assaying whether an agent affects heart rate using a cardiac cell that is *in vitro* and/or the doubts expressed in the art of record.

In conclusion, the as-filed specification and claims coupled with the art of record at the time the invention was made do not provide sufficient guidance and/or evidence to reasonably enable one skilled in the art to make and use any of the claimed methods. In view of the art of record that measuring a heart rate using a cardiac cell in vitro was considered unpredictable at the time the invention was made, and given the lack of sufficient guidance as to practice the methods cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicant's disclosure.

Applicant's arguments with respect to claims 1, 2, 3, 9, 11, 15, 16 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments, see paper no. 7, filed 7/7/03, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection to the claims 13, 14, 15, and 16 has been withdrawn because of the amendment to claim 15 and the

cancellation of claims 13 and 14. However, upon further consideration, a new ground(s) of rejection is made in view of the addition of claims 32-35.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the heart". There is insufficient antecedent basis for this limitation in the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER